

As used herein, the term "enzyme" refers to molecules or molecule aggregates that are responsible for catalyzing chemical and biological reactions. Such molecules are typically proteins but can also be short peptides, RNAs, or other molecules.

As used herein, the term "competitor" refers to any means capable of reducing the rate of a reaction. In some embodiments, competitors include, but are not limited to competing substrates that compete with another substrate for access to an enzyme active site. The competing substrate may have greater or lesser affinity for the active site than the other substrate. In other embodiments, competitors include, but are not limited to trapping agents that prevent a substrate from reacting with an enzyme or prevent a reaction product from being detected.

As used herein, the term "substantially depleted" refers to a competing substrate that has reacted with an enzyme to such a degree that other substrates are capable of accessing the enzyme at significant levels (*e.g.*, detectable levels).

As used herein, the term "sol-gel" refers to preparations composed of porous metal oxide glass structures. Such structures can have biological (*e.g.*, enzymes) or other material entrapped within the porous structures. The phrase "sol-gel matrices" refers to the structures comprising the porous metal oxide glass with or without entrapped material. The term "sol-gel material" refers to any material prepared by the sol-gel process including the glass material itself and any entrapped material within the porous structure of the glass. As used herein, the term "sol-gel method" refers to any method that results in the production of porous metal oxide glass. In some embodiments, "sol-gel method" refers to such methods conducted under mild temperature conditions. The terms "sol-gel glass" and "metal oxide glass" refer to glass material prepared by the sol-gel method and include inorganic material or mixed organic/inorganic material. The materials used to produce the glass can include, but are not limited to, aluminates, aluminosilicates, titanates, ormosils (organically modified silanes), and other metal oxides.

As used herein, the term "direct colorimetric detection" refers to the detection of color changes without the aid of an intervening processing step (*e.g.*, without conversion of a color change into an electronic signal that is processed by an

interpreting device). It is intended that the term encompass visual observing (e.g., observing with the human eye).

As used herein, the term "chromophore" refers to molecules or molecular groups responsible for the color of a compound, material, or sample.

5 As used herein, the term "aqueous" refers to a liquid mixture containing water, among other components.

As used herein, the term "breakable barrier" refers to a barrier between chambers or wells that can be broken, for example, by bending, compressing, heating, snapping, twisting, or other disruptions, such that the contents of the chambers or wells have access to one another.

10 As used herein, the term "indicator" refers to a detectable signal that indicates the introduction of sufficient sample to a reaction means for a desired (e.g., detectable and reliable) reaction to take place.

15 As used herein, the term "protective encasement" refers to a thin covering, wrapping or shielding comprising a material that acts to protect a composition such as a reaction means (e.g., to extend the shelf-life of the reaction means).

20 As used herein, the term "communication facilitating agent" refers to an agent that allows an individual to initiate a communication with another individual or with another entity. Communication facilitating agents include, but are not limited to, phone cards, pre-paid dial-in phone numbers, Internet access information, etc. that allow one to initiate a communication with another party (e.g., a party capable of providing the individual transportation).

As used herein, the term "low-moisture environment" refers to environments with a lower moisture content than the ambient environment.

25 As used herein, the term "sleeve," when referring to delivery systems, refers to a pouch-like enclosure comprising at least two, preferably three, sealed sides to provide an opening for the insertion, removal, enclosure, and storage of another item. In some preferred embodiments, the sleeve is contained on a credit-card sized delivery system (e.g., approximately 9 cm x 6 cm x 2 mm). One embodiment of such a sleeve

containing delivery system is shown in Figure 14. The sleeve portion of the delivery system may be made of any material, including, but not limited to, plastic, paper, cardboard, and the like.

As used herein, the term "entrained" refers to materials that are integrated, attached, or in fixed contact with other materials. For example, entrained desiccants are desiccants that are mixed within another material or attached or fixed to another material (e.g., attached or fixed as a lining within a container).

As used herein, the term "time-consuming materials" refers to materials other than assay tests or delivery systems that can be used to occupy an individual's time (e.g., for minutes to hours). Such materials may comprise objects or may be written material or other text. Such written material may, in some embodiments, be included on assay tests or delivery systems. Examples of time-consuming materials include, but are not limited to puzzles, games, Internet access devices. Time consuming materials find use, for example, in passing time while waiting for one's blood alcohol concentration to drop.

## **DETAILED DESCRIPTION OF THE INVENTION**

The present invention provides systems for determining the presence of or level of an analyte in a sample. For example, the present invention provides qualitative and quantitative detection assays that determine if an analyte is present in a sample at or above one or more specific concentration levels.

In preferred embodiments of the present invention, the test assay comprises an oral test assay. In particularly preferred embodiments, the test assay is an easy-to-use test strip comprising a reaction site at one end. In some preferred embodiments, the reaction site is placed into the mouth of an individual and is saturated with saliva. If the targeted analyte is present in the saliva, a detectable signal is produced, indicating the presence of, or concentration of, the analyte. In some preferred embodiments, the detectable signal is detectable by the human eye (e.g., a viewable color change). However, the present invention includes detectable signals that are read by a device. Because the reaction site is placed in the mouth, it is preferred that components of the